

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendant
PFIZER INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

| | |
|--|--------------------------------|
| IN RE BEXTRA AND CELEBREX MARKETING,) | MDL Docket No. 1699 |
| SALES PRACTICES AND PRODUCTS) | |
| LIABILITY LITIGATION) | CASE NO 3:08-cv-3357-CRB |
| <i>This document relates to</i>) | |
| JIMMIE L. BROCKMAN,) | PFIZER INC.'S ANSWER TO |
| Plaintiff,) | COMPLAINT |
| vs.) | JURY DEMAND ENDORSED |
| PFIZER, INC.,) | HEREIN |
| Defendant.) | |

NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer" or "Defendant") and files this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally. Defendant may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra®.

II.

ORIGINAL ANSWER**Response to Allegations Regarding Jurisdiction**

1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's citizenship and the amount in controversy, and, therefore, denies the same. However, Defendant admits that Plaintiff claims that the parties are diverse and that the amount in controversy exceeds \$75,000, exclusive of interests and costs.

Response to Allegations Regarding the Nature of the Case

2. Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining allegations in this paragraph of the Complaint.

3. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

4. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the Complaint.

5. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

6. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

7. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Parties

8. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

9. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph of the Complaint.

10. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies that Bextra® caused Plaintiff injury or damages and denies the remaining allegations in this paragraph of the Complaint.

11. Defendant admits that it is a Delaware corporation with its principal place of business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

12. Defendant admits that it is a Delaware corporation with its principal place of business in New York. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

13. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

14. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

15. Defendant admits that it does business in New York. Defendant denies the remaining allegations in this paragraph of the Complaint.

1 16. Defendant admits that it does business in the United States, including New York.
2 Defendant denies the remaining allegations in this paragraph of the Complaint.

3 17. Defendant admits that, during certain periods of time, it marketed and co-promoted
4 Bextra® in the United States to be prescribed by healthcare providers who are by law
5 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
6 the remaining allegations in this paragraph of the Complaint.

7 18. Defendant admits that it is registered to do and does business in New York. Defendant
8 is without knowledge or information sufficient to form a belief as to the judicial district in
9 which the asserted claims allegedly arose, and, therefore, denies the same. Defendant denies
10 any wrongful conduct, denies committing a tort in the States of New York or California, and
11 denies the remaining allegations in this paragraph of the Complaint.

12 **Response to Factual Allegations**

13 19. Defendant admits that Bextra® was approved by the FDA, on November 16, 2001.
14 Defendant admits, as indicated in the package insert approved by the FDA, that Bextra® is
15 indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid
16 arthritis, as well as for the treatment of primary dysmenorrhea. Defendant denies the remaining
17 allegations in this paragraph of the Complaint.

18 20. Defendant admits that Bextra® is in a class of drugs that is, at times, referred to as non-
19 steroidal anti-inflammatory drugs (“NSAIDs”). Defendant states that the remaining allegations
20 in this paragraph of the Complaint are not directed toward Defendant, and, therefore, no
21 response is required. To the extent that a response is deemed required, Defendant states that
22 Plaintiff fails to provide the context for the remaining allegations in this paragraph of the
23 Complaint. Defendant is therefore without knowledge or information sufficient to form a belief
24 as to the truth of such allegations, and, therefore, denies the same.

25 21. Defendant states that, as stated in the FDA-approved labeling for Bextra®, “[t]he
26 mechanism of action is believed to be due to inhibition of prostaglandin synthesis primarily
27 through inhibition of cyclooxygenase-2 (COX-2). At therapeutic plasma concentrations in
28 humans valdecoxib does not inhibit cyclooxygenase-1 (COX-1).” Defendant states that the

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1 remaining allegations in this paragraph of the Complaint are not directed toward Defendant,
2 and, therefore, no response is required. To the extent that a response is deemed required,
3 Defendant states that Plaintiff fails to provide the context for the remaining allegations in this
4 paragraph of the Complaint. Defendant is therefore without knowledge or information
5 sufficient to form a belief as to the truth of such allegations, and, therefore, denies the same.

6 22. Defendant states that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
11 of the Complaint.

12 23. Defendant states that the referenced media statement speaks for itself and respectfully
13 refers the Court to the media statement for its actual language and full text. Any attempt to
14 characterize the media statement is denied. Defendant denies the remaining allegations in this
15 paragraph of the Complaint.

16 24. Defendant admits that the sale of Bextra® was voluntarily suspended in the U.S.
17 market as of April 7, 2005. Defendant denies any wrongful conduct and denies the remaining
18 allegations in this paragraph of the Complaint.

19 25. Defendant admits that, during certain periods of time, it marketed and co-promoted
20 Bextra® in the United States to be prescribed by healthcare providers who are by law
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
22 admits, as indicated in the package insert approved by the FDA, that Bextra® is indicated for
23 use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as
24 well as for the treatment of primary dysmenorrhea. Defendant denies the remaining
25 allegations in this paragraph of the Complaint.

26 26. Defendant is without knowledge or information sufficient to form a belief as to the truth
27 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
28 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective

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1 when used in accordance with its FDA-approved prescribing information. Defendant states that
2 the potential effects of Bextra® were and are adequately described in its FDA-approved
3 prescribing information, which was at all times adequate and comported with applicable
4 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
5 allegations in this paragraph of the Complaint.

6 27. Defendant is without knowledge or information sufficient to form a belief as to the truth
7 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
8 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
9 when used in accordance with its FDA-approved prescribing information. Defendant states that
10 the potential effects of Bextra® were and are adequately described in its FDA-approved
11 prescribing information, which was at all times adequate and comported with applicable
12 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
13 allegations in this paragraph of the Complaint.

14 28. Defendant is without knowledge or information sufficient to form a belief as to the truth
15 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
16 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
17 when used in accordance with its FDA-approved prescribing information. Defendant states that
18 the potential effects of Bextra® were and are adequately described in its FDA-approved
19 prescribing information, which was at all times adequate and comported with applicable
20 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is
21 unreasonably dangerous, and denies the remaining allegations in this paragraph of the
22 Complaint.

23 29. Defendant is without knowledge or information sufficient to form a belief as to the truth
24 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
25 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
26 when used in accordance with its FDA-approved prescribing information. Defendant states that
27 the potential effects of Bextra® were and are adequately described in its FDA-approved
28 prescribing information, which was at all times adequate and comported with applicable

standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra® caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Negligence and Negligence Per Se

30. Defendant incorporates by reference its responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

31. Defendant admits that it had duties as are imposed by law but denies having breached such duties. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the remaining allegations in this paragraph of the Complaint.

32. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the remaining allegations in this paragraph of the Complaint.

33. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®, and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint, including all subparts.

34. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
4 of the Complaint.

5 35. Defendant states that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendant states that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and
10 denies the remaining allegations in this paragraph of the Complaint.

11 36. Defendant is without knowledge or information sufficient to form a belief as to the truth
12 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
13 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
14 when used in accordance with its FDA-approved prescribing information. Defendant states that
15 the potential effects of Bextra® were and are adequately described in its FDA-approved
16 prescribing information, which was at all times adequate and comported with applicable
17 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
18 Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the
19 Complaint.

20 37. Defendant is without knowledge or information sufficient to form a belief as to the truth
21 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
22 and, therefore, denies the same. Defendant admits that, during certain periods of time, it
23 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
24 providers who are by law authorized to prescribe drugs in accordance with their approval by the
25 FDA. Defendant states that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendant states that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendant admits that the sale of Bextra® was voluntarily suspended in the U.S. market as of
2 April 7, 2005. Defendant denies any wrongful conduct, denies that Bextra® is unreasonably
3 dangerous, and denies the remaining allegations in this paragraph of the Complaint.

4 38. Defendant is without knowledge or information sufficient to form a belief as to the truth
5 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
6 and, therefore, denies the same. Defendant denies any wrongful conduct, denies that Bextra®
7 caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the
8 Complaint.

9 39. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
10 damages, and denies the remaining allegations in this paragraph of the Complaint.

11 40. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
12 damages, and denies the remaining allegations in this paragraph of the Complaint.

13 41. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
14 damages, and denies the remaining allegations in this paragraph of the Complaint.

15 42. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
16 damages, and denies the remaining allegations in this paragraph of the Complaint.

17 **Response to Second Cause of Action: Strict Products Liability**

18 43. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
19 Complaint as if fully set forth herein.

20 44. Defendant is without knowledge or information sufficient to form a belief as to the truth
21 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
22 and, therefore, denies the same. Defendant admits that, during certain periods of time, it
23 marketed and co-promoted Bextra® in the United States to be prescribed by healthcare
24 providers who are by law authorized to prescribe drugs in accordance with their approval by the
25 FDA. Defendant denies the remaining allegations in this paragraph of the Complaint.

26 45. Defendant admits that, during certain periods of time, it marketed and co-promoted
27 Bextra® in the United States to be prescribed by healthcare providers who are by law
28 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states

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1 that, in the ordinary case, Bextra® was expected to reach users and consumers without
2 substantial change from the time of sale. Defendant denies the remaining allegations in this
3 paragraph of the Complaint.

4 46. Defendant is without knowledge or information sufficient to form a belief as to the truth
5 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
6 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
7 when used in accordance with its FDA-approved prescribing information. Defendant states that
8 the potential effects of Bextra® were and are adequately described in its FDA-approved
9 prescribing information, which was at all times adequate and comported with applicable
10 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is
11 defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of
12 the Complaint.

13 47. Defendant states that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendant states that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
18 remaining allegations in this paragraph of the Complaint.

19 48. Defendant is without knowledge or information sufficient to form a belief as to the truth
20 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
21 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
22 when used in accordance with its FDA-approved prescribing information. Defendant denies
23 any wrongful conduct, denies that Bextra® is defective or unreasonably dangerous, and denies
24 the remaining allegations in this paragraph of the Complaint.

25 49. Defendant states that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendant denies any wrongful conduct,
27 denies that Bextra® is defective or unreasonably dangerous, and denies the remaining
28 allegations in this paragraph of the Complaint.

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1 50. Defendant states that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendant denies any wrongful conduct,
3 denies that Bextra® is defective, and denies the remaining allegations in this paragraph of the
4 Complaint.

5 51. Defendant is without knowledge or information sufficient to form a belief as to the truth
6 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
7 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
8 when used in accordance with its FDA-approved prescribing information. Defendant states that
9 the potential effects of Bextra® were and are adequately described in its FDA-approved
10 prescribing information, which was at all times adequate and comported with applicable
11 standards of care and law. Defendant denies the remaining allegations in this paragraph of the
12 Complaint.

13 52. Defendant is without knowledge or information sufficient to form a belief as to the truth
14 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
15 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
16 when used in accordance with its FDA-approved prescribing information. Defendant states that
17 the potential effects of Bextra® were and are adequately described in its FDA-approved
18 prescribing information, which was at all times adequate and comported with applicable
19 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
20 allegations in this paragraph of the Complaint.

21 53. Defendant states that this paragraph of the Complaint contains legal contentions to
22 which no response is required. To the extent that a response is deemed required, Defendant
23 admits that it had duties as are imposed by law but denies having breached such duties.
24 Defendant states that Bextra® was and is safe and effective when used in accordance with its
25 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
26 were and are adequately described in its FDA-approved prescribing information, which was at
27 all times adequate and comported with applicable standards of care and law. Defendant denies
28 any wrongful conduct, denies that Bextra® is unreasonably dangerous, and denies the

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1 remaining allegations in this paragraph of the Complaint.

2 54. Defendant states that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendant states that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and
7 denies the remaining allegations in this paragraph of the Complaint.

8 55. Defendant is without knowledge or information sufficient to form a belief as to the truth
9 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
10 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
11 when used in accordance with its FDA-approved prescribing information. Defendant states that
12 the potential effects of Bextra® were and are adequately described in its FDA-approved
13 prescribing information, which was at all times adequate and comported with applicable
14 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is
15 defective or unreasonably dangerous, denies that Bextra® caused Plaintiff injury or damages,
16 and denies the remaining allegations in this paragraph of the Complaint.

17 56. Defendant states that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendant states that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
22 remaining allegations in this paragraph of the Complaint.

23 57. Defendant states that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendant states that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
28 remaining allegations in this paragraph of the Complaint.

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1 58. Defendant states that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendant states that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
6 remaining allegations in this paragraph of the Complaint.

7 59. Defendant is without knowledge or information sufficient to form a belief as to the truth
8 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
9 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
10 when used in accordance with its FDA-approved prescribing information. Defendant states that
11 the potential effects of Bextra® were and are adequately described in its FDA-approved
12 prescribing information, which was at all times adequate and comported with applicable
13 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is
14 defective, and denies the remaining allegations in this paragraph of the Complaint.

15 60. Defendant states that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendant states that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.
19 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®
20 caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the
21 Complaint.

22 61. Defendant states that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendant states that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
27 remaining allegations in this paragraph of the Complaint.

28 62. Defendant states that Bextra® was and is safe and effective when used in accordance

1 with its FDA-approved prescribing information. Defendant states that the potential effects of
2 Bextra® were and are adequately described in its FDA-approved prescribing information,
3 which was at all times adequate and comported with applicable standards of care and law.
4 Defendant denies any wrongful conduct, denies that Bextra® is defective, denies that Bextra®
5 caused Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the
6 Complaint.

7 63. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
8 damages, and denies the remaining allegations in this paragraph of the Complaint.

9 64. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
10 damages, and denies the remaining allegations in this paragraph of the Complaint.

11 65. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
12 damages, and denies the remaining allegations in this paragraph of the Complaint.

13 **Response to Third Cause of Action: Breach of Express Warranty**

14 66. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
15 Complaint as if fully set forth herein.

16 67. Defendant states that Bextra® was and is safe and effective when used in accordance
17 with its FDA-approved prescribing information. Defendant states that the potential effects of
18 Bextra® were and are adequately described in its FDA-approved prescribing information,
19 which was at all times adequate and comported with applicable standards of care and law.
20 Defendant admits that it provided FDA-approved prescribing information regarding Bextra®.
21 Defendant denies the remaining allegations in this paragraph of the Complaint.

22 68. Defendant states that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendant states that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
27 of the Complaint.

28 69. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or

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1 damages, and denies the remaining allegations in this paragraph of the Complaint.

2 70. Defendant admits that it provided FDA-approved prescribing information regarding
3 Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.

4 71. Defendant admits that it provided FDA-approved prescribing information regarding
5 Bextra®. Defendant denies the remaining allegations in this paragraph of the Complaint.

6 72. Defendant states that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
11 remaining allegations in this paragraph of the Complaint.

12 73. Defendant states that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendant states that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendant admits that it provided FDA-approved prescribing information regarding Bextra®.
17 Defendant denies the remaining allegations in this paragraph of the Complaint.

18 74. Defendant states that Bextra® was and is safe and effective when used in accordance
19 with its FDA-approved prescribing information. Defendant states that the potential effects of
20 Bextra® were and are adequately described in its FDA-approved prescribing information,
21 which was at all times adequate and comported with applicable standards of care and law.
22 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
23 of the Complaint.

24 75. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
25 damages, and denies the remaining allegations in this paragraph of the Complaint.

26 76. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
27 damages, and denies the remaining allegations in this paragraph of the Complaint.

28 77. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or

1 damages, and denies the remaining allegations in this paragraph of the Complaint.

2 78. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
3 damages, and denies the remaining allegations in this paragraph of the Complaint.

4 **Response to Fourth Cause of Action: Breach of Implied Warranties**

5 79. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
6 Complaint as if fully set forth herein.

7 80. Defendant admits that, during certain periods of time, it marketed and co-promoted
8 Bextra® in the United States to be prescribed by healthcare providers who are by law
9 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
10 the remaining allegations in this paragraph of the Complaint.

11 81. Defendant is without knowledge or information sufficient to form a belief as to the truth
12 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
13 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
14 when used in accordance with its FDA-approved prescribing information. Defendant states that
15 the potential effects of Bextra® were and are adequately described in its FDA-approved
16 prescribing information, which was at all times adequate and comported with applicable
17 standards of care and law. Defendant admits that it provided FDA-approved prescribing
18 information regarding Bextra®. Defendant denies the remaining allegations in this paragraph
19 of the Complaint.

20 82. Defendant states that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendant states that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendant admits that it provided FDA-approved prescribing information regarding Bextra®.
25 Defendant denies the remaining allegations in this paragraph of the Complaint.

26 83. Defendant states that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendant states that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant denies any wrongful conduct, denies that Bextra® is defective or unreasonably
3 dangerous, and denies the remaining allegations in this paragraph of the Complaint.

4 84. Defendant is without knowledge or information sufficient to form a belief as to the truth
5 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
6 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
7 when used in accordance with its FDA-approved prescribing information. Defendant states that
8 the potential effects of Bextra® were and are adequately described in its FDA-approved
9 prescribing information, which was at all times adequate and comported with applicable
10 standards of care and law. Defendant admits that it provided FDA-approved prescribing
11 information regarding Bextra®. Defendant denies the remaining allegations in this paragraph
12 of the Complaint.

13 85. Defendant is without knowledge or information sufficient to form a belief as to the truth
14 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
15 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
16 when used in accordance with its FDA-approved prescribing information. Defendant states that
17 the potential effects of Bextra® were and are adequately described in its FDA-approved
18 prescribing information, which was at all times adequate and comported with applicable
19 standards of care and law. Defendant admits that it provided FDA-approved prescribing
20 information regarding Bextra®. Defendant denies the remaining allegations in this paragraph
21 of the Complaint.

22 86. Defendant states that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendant states that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendant states that, in the ordinary case, Bextra® was expected to reach users and consumers
27 without substantial change from the time of sale. Defendant denies any wrongful conduct,
28 denies that Bextra® is defective or unreasonably dangerous, and denies remaining allegations in

1 this paragraph of the Complaint.

2 87. Defendant states that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendant states that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendant denies any wrongful conduct and denies remaining allegations in this paragraph of
7 the Complaint.

8 88. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
9 damages, and denies the remaining allegations in this paragraph of the Complaint.

10 89. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
11 damages, and denies the remaining allegations in this paragraph of the Complaint.

12 90. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
13 damages, and denies the remaining allegations in this paragraph of the Complaint.

14 91. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
15 damages, and denies the remaining allegations in this paragraph of the Complaint.

16 **Response to Fifth Cause of Action: Fraudulent Misrepresentation**

17 92. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
18 Complaint as if fully set forth herein.

19 93. Defendant states that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendant states that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
24 of the Complaint.

25 94. Defendant states that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendant states that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
2 of the Complaint.

3 95. Defendant states that Bextra® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendant states that the potential effects of
5 Bextra® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
8 of the Complaint.

9 96. Defendant is without knowledge or information sufficient to form a belief as to the truth
10 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
11 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
12 when used in accordance with its FDA-approved prescribing information. Defendant states that
13 the potential effects of Bextra® were and are adequately described in its FDA-approved
14 prescribing information, which was at all times adequate and comported with applicable
15 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
16 allegations in this paragraph of the Complaint.

17 97. Defendant is without knowledge or information sufficient to form a belief as to the truth
18 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
19 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
20 when used in accordance with its FDA-approved prescribing information. Defendant states that
21 the potential effects of Bextra® were and are adequately described in its FDA-approved
22 prescribing information, which was at all times adequate and comported with applicable
23 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® caused
24 Plaintiff injury or damages, and denies the remaining allegations in this paragraph of the
25 Complaint.

26 98. Defendant states that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendant states that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
3 remaining allegations in this paragraph of the Complaint.

4 99. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant states that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
9 of the Complaint.

10 100. Defendant admits that, during certain periods of time, it marketed and co-promoted
11 Bextra® in the United States to be prescribed by healthcare providers who are by law
12 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
13 any wrongful conduct, denies that Bextra® caused Plaintiff injury or damages, and denies the
14 remaining allegations in this paragraph of the Complaint.

15 101. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
16 damages, and denies the remaining allegations in this paragraph of the Complaint.

17 102. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
18 damages, and denies the remaining allegations in this paragraph of the Complaint.

19 103. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
20 damages, and denies the remaining allegations in this paragraph of the Complaint.

21 **Response to Sixth Cause of Action: Fraudulent Concealment**

22 104. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
23 Complaint as if fully set forth herein.

24 105. Defendant states that Bextra® was and is safe and effective when used in accordance
25 with its FDA-approved prescribing information. Defendant states that the potential effects of
26 Bextra® were and are adequately described in its FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

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1 of the Complaint.

2 106. Defendant states that Bextra® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendant states that the potential effects of
4 Bextra® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
7 of the Complaint.

8 107. Defendant states that Bextra® was and is safe and effective when used in accordance
9 with its FDA-approved prescribing information. Defendant states that the potential effects of
10 Bextra® were and are adequately described in its FDA-approved prescribing information,
11 which was at all times adequate and comported with applicable standards of care and law.
12 Defendant denies any wrongful conduct, denies that Bextra® is defective, and denies the
13 remaining allegations in this paragraph of the Complaint, including all subparts.

14 108. Defendant states that this paragraph of the Complaint contains legal contentions to
15 which no response is required. To the extent that a response is deemed required, Defendant
16 admits that it had duties as are imposed by law but denies having breached such duties.
17 Defendant states that Bextra® was and is safe and effective when used in accordance with its
18 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
19 were and are adequately described in its FDA-approved prescribing information, which was at
20 all times adequate and comported with applicable standards of care and law. Defendant denies
21 any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

22 109. Defendant is without knowledge or information sufficient to form a belief as to the truth
23 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
24 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
25 when used in accordance with its FDA-approved prescribing information. Defendant states that
26 the potential effects of Bextra® were and are adequately described in its FDA-approved
27 prescribing information, which was at all times adequate and comported with applicable
28 standards of care and law. Defendant denies any wrongful conduct, denies that Bextra® is

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1 defective, denies that Bextra® caused Plaintiff injury or damages, and denies the remaining
2 allegations in this paragraph of the Complaint.

3 110. Defendant is without knowledge or information sufficient to form a belief as to the truth
4 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
5 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
6 when used in accordance with its FDA-approved prescribing information. Defendant states that
7 the potential effects of Bextra® were and are adequately described in its FDA-approved
8 prescribing information, which was at all times adequate and comported with applicable
9 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
10 allegations in this paragraph of the Complaint.

11 111. Defendant states that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendant states that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
16 of the Complaint.

17 112. Defendant is without knowledge or information sufficient to form a belief as to the truth
18 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
19 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
20 when used in accordance with its FDA-approved prescribing information. Defendant states that
21 the potential effects of Bextra® were and are adequately described in its FDA-approved
22 prescribing information, which was at all times adequate and comported with applicable
23 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
24 allegations in this paragraph of the Complaint.

25 113. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
26 damages, and denies the remaining allegations in this paragraph of the Complaint.

27 114. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
28 damages, and denies the remaining allegations in this paragraph of the Complaint.

1 115. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
2 damages, and denies the remaining allegations in this paragraph of the Complaint.

3 **Response to Seventh Cause of Action: Negligent Misrepresentation**

4 116. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
5 Complaint as if fully set forth herein.

6 117. Defendant states that this paragraph of the Complaint contains legal contentions to
7 which no response is required. To the extent that a response is deemed required, Defendant
8 admits that it had duties as are imposed by law but denies having breached such duties.
9 Defendant states that Bextra® was and is safe and effective when used in accordance with its
10 FDA-approved prescribing information. Defendant states that the potential effects of Bextra®
11 were and are adequately described in its FDA-approved prescribing information, which was at
12 all times adequate and comported with applicable standards of care and law. Defendant denies
13 the remaining allegations in this paragraph of the Complaint.

14 118. Defendant states that Bextra® was and is safe and effective when used in accordance
15 with its FDA-approved prescribing information. Defendant states that the potential effects of
16 Bextra® were and are adequately described in its FDA-approved prescribing information,
17 which was at all times adequate and comported with applicable standards of care and law.
18 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
19 of the Complaint.

20 119. Defendant states that Bextra® was and is safe and effective when used in accordance
21 with its FDA-approved prescribing information. Defendant states that the potential effects of
22 Bextra® were and are adequately described in its FDA-approved prescribing information,
23 which was at all times adequate and comported with applicable standards of care and law.
24 Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and
25 denies the remaining allegations in this paragraph of the Complaint.

26 120. Defendant states that Bextra® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendant states that the potential effects of
28 Bextra® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
3 of the Complaint.

4 121. Defendant states that Bextra® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendant states that the potential effects of
6 Bextra® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendant denies any wrongful conduct, denies that Bextra® is unreasonably dangerous, and
9 denies the remaining allegations in this paragraph of the Complaint.

10 122. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
11 damages, and denies the remaining allegations in this paragraph of the Complaint.

12 123. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
13 damages, and denies the remaining allegations in this paragraph of the Complaint.

14 124. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
15 damages, and denies the remaining allegations in this paragraph of the Complaint.

16 **Response to Eighth Cause of Action: Fraud and Deceit**

17 125. Defendant incorporates by reference its responses to each paragraph of Plaintiff's
18 Complaint as if fully set forth herein.

19 126. Defendant states that Plaintiff fails to provide the proper context for the allegations in
20 this paragraph of the Complaint. Defendant therefore lacks knowledge or information
21 sufficient to form a belief as to the truth of such allegations and, therefore, denies the same.

22 127. Defendant states that Bextra® was and is safe and effective when used in accordance
23 with its FDA-approved prescribing information. Defendant states that the potential effects of
24 Bextra® were and are adequately described in its FDA-approved prescribing information,
25 which was at all times adequate and comported with applicable standards of care and law.
26 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
27 of the Complaint.

28 128. Defendant denies any wrongful conduct and denies the remaining allegations in this

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1 paragraph of the Complaint.

2 129. Defendant states that this paragraph of the Complaint contains legal contentions to
3 which no response is required. To the extent that a response is deemed required, Defendant
4 admits that it had duties as are imposed by law but denies having breached such duties.
5 Defendant denies the remaining allegations in this paragraph of the Complaint.

6 130. Defendant states that Bextra® was and is safe and effective when used in accordance
7 with its FDA-approved prescribing information. Defendant states that the potential effects of
8 Bextra® were and are adequately described in its FDA-approved prescribing information,
9 which was at all times adequate and comported with applicable standards of care and law.
10 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
11 of the Complaint.

12 131. Defendant states that Bextra® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendant states that the potential effects of
14 Bextra® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendant denies the remaining allegations in this paragraph of the Complaint.

17 132. Defendant states that Bextra® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendant states that the potential effects of
19 Bextra® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
22 of the Complaint.

23 133. Defendant states that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendant states that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
28 of the Complaint.

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1 134. Defendant states that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendant states that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
6 of the Complaint.

7 135. Defendant states that Bextra® was and is safe and effective when used in accordance
8 with its FDA-approved prescribing information. Defendant states that the potential effects of
9 Bextra® were and are adequately described in its FDA-approved prescribing information,
10 which was at all times adequate and comported with applicable standards of care and law.
11 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
12 of the Complaint.

13 136. Defendant states that Bextra® was and is safe and effective when used in accordance
14 with its FDA-approved prescribing information. Defendant states that the potential effects of
15 Bextra® were and are adequately described in its FDA-approved prescribing information,
16 which was at all times adequate and comported with applicable standards of care and law.
17 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
18 of the Complaint.

19 137. Defendant states that Bextra® was and is safe and effective when used in accordance
20 with its FDA-approved prescribing information. Defendant states that the potential effects of
21 Bextra® were and are adequately described in its FDA-approved prescribing information,
22 which was at all times adequate and comported with applicable standards of care and law.
23 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
24 of the Complaint.

25 138. Defendant states that Bextra® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendant states that the potential effects of
27 Bextra® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
2 of the Complaint.

3 139. Defendant states that Bextra® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendant states that the potential effects of
5 Bextra® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.

7 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
8 of the Complaint.

9 140. Defendant states that Bextra® was and is safe and effective when used in accordance
10 with its FDA-approved prescribing information. Defendant states that the potential effects of
11 Bextra® were and are adequately described in its FDA-approved prescribing information,
12 which was at all times adequate and comported with applicable standards of care and law.

13 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
14 of the Complaint.

15 141. Defendant states that Bextra® was and is safe and effective when used in accordance
16 with its FDA-approved prescribing information. Defendant states that the potential effects of
17 Bextra® were and are adequately described in its FDA-approved prescribing information,
18 which was at all times adequate and comported with applicable standards of care and law.

19 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
20 of the Complaint.

21 142. Defendant states that Bextra® was and is safe and effective when used in accordance
22 with its FDA-approved prescribing information. Defendant states that the potential effects of
23 Bextra® were and are adequately described in its FDA-approved prescribing information,
24 which was at all times adequate and comported with applicable standards of care and law.

25 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
26 of the Complaint.

27 143. Defendant states that Bextra® was and is safe and effective when used in accordance
28 with its FDA-approved prescribing information. Defendant states that the potential effects of

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1 Bextra® were and are adequately described in its FDA-approved prescribing information,
2 which was at all times adequate and comported with applicable standards of care and law.
3 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
4 of the Complaint.

5 144. Defendant states that Bextra® was and is safe and effective when used in accordance
6 with its FDA-approved prescribing information. Defendant states that the potential effects of
7 Bextra® were and are adequately described in its FDA-approved prescribing information,
8 which was at all times adequate and comported with applicable standards of care and law.
9 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
10 of the Complaint.

11 145. Defendant states that Bextra® was and is safe and effective when used in accordance
12 with its FDA-approved prescribing information. Defendant states that the potential effects of
13 Bextra® were and are adequately described in its FDA-approved prescribing information,
14 which was at all times adequate and comported with applicable standards of care and law.
15 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
16 of the Complaint.

17 146. Defendant denies any wrongful conduct and denies the remaining allegations in this
18 paragraph of the Complaint.

19 147. Defendant admits that, during certain periods of time, it marketed and co-promoted
20 Bextra® in the United States to be prescribed by healthcare providers who are by law
21 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
22 the remaining allegations in this paragraph of the Complaint.

23 148. Defendant states that Bextra® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendant states that the potential effects of
25 Bextra® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
28 of the Complaint.

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1 149. Defendant states that Bextra® was and is safe and effective when used in accordance
2 with its FDA-approved prescribing information. Defendant states that the potential effects of
3 Bextra® were and are adequately described in its FDA-approved prescribing information,
4 which was at all times adequate and comported with applicable standards of care and law.
5 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph
6 of the Complaint.

7 150. Defendant is without knowledge or information sufficient to form a belief as to the truth
8 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®,
9 and, therefore, denies the same. Defendant states that Bextra® was and is safe and effective
10 when used in accordance with its FDA-approved prescribing information. Defendant states that
11 the potential effects of Bextra® were and are adequately described in its FDA-approved
12 prescribing information, which was at all times adequate and comported with applicable
13 standards of care and law. Defendant denies any wrongful conduct and denies the remaining
14 allegations in this paragraph of the Complaint.

15 151. Defendant denies any wrongful conduct and denies the remaining allegations in this
16 paragraph of the Complaint.

17 152. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
18 damages, and denies the remaining allegations in this paragraph of the Complaint.

19 153. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
20 damages, and denies the remaining allegations in this paragraph of the Complaint.

21 154. Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
22 damages, and denies the remaining allegations in this paragraph of the Complaint.

23 **Response to Prayer for Relief**

24 Defendant denies any wrongful conduct, denies that Bextra® caused Plaintiff injury or
25 damages, and denies the remaining allegations in Plaintiff's Prayer for Relief, including all
26 subparts.

1 **III.**

2 **GENERAL DENIAL**

3 Defendant denies the allegations and/or legal conclusions set forth in Plaintiff's Complaint that
4 have not been previously admitted, denied, or explained.

5 **IV.**

6 **AFFIRMATIVE DEFENSES**

7 Defendant reserves the right to rely upon any of the following or additional defenses to
8 claims asserted by Plaintiff to the extent that such defenses are supported by information
9 developed through discovery or evidence at trial. Defendant affirmatively shows that:

10 **First Defense**

11 1. The Complaint fails to state a claim upon which relief can be granted.

12 **Second Defense**

13 2. Bextra® is prescription medical product. The federal government has preempted the
14 field of law applicable to the labeling and warning of prescription medical products.
15 Defendant's labeling and warning of Bextra® was at all times in compliance with applicable
16 federal law. Plaintiff's causes of action against Defendant, therefore, fail to state a claim upon
17 which relief can be granted; such claims, if allowed, would conflict with applicable federal
18 law and violate the Supremacy Clause of the United States Constitution.

19 **Third Defense**

20 3. At all relevant times, Defendant provided proper warnings, information and
21 instructions for the drug in accordance with generally recognized and prevailing standards in
22 existence at the time.

23 **Fourth Defense**

24 4. At all relevant times, Defendant's warnings and instructions with respect to the use of
25 Bextra® conformed to the generally recognized, reasonably available, and reliable state of
26 knowledge at the time the drug was manufactured, marketed and distributed.

27 **Fifth Defense**

28 5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the

1 applicable Statute of Limitations, and same is pled in full bar of any liability as to Defendant.

2 **Sixth Defense**

3 6. Plaintiff's action is barred by the statute of repose.

4 **Seventh Defense**

5 7. Plaintiff's claims against Defendant are barred to the extent Plaintiff was contributorily
6 negligent, actively negligent or otherwise failed to mitigate Plaintiff's damages, and any
7 recovery by Plaintiff should be diminished accordingly.

8 **Eighth Defense**

9 8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or
10 omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the
11 part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not
12 liable in any way.

13 **Ninth Defense**

14 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,
15 intervening causes for which Defendant cannot be liable.

16 **Tenth Defense**

17 10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were
18 proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or
19 act of God.

20 **Eleventh Defense**

21 11. Defendant affirmatively denies that it violated any duty owed to Plaintiff.

22 **Twelfth Defense**

23 12. A manufacturer has no duty to warn patients or the general public of any risk,
24 contraindication, or adverse effect associated with the use of a prescription medical product.
25 Rather, the law requires that all such warnings and appropriate information be given to the
26 prescribing physician and the medical profession, which act as a "learned intermediary" in
27 determining the use of the product. Bextra® is a prescription medical product, available only
28 on the order of a licensed physician. Bextra® provided adequate warnings to Plaintiff's

1 treating and prescribing physicians.

2 **Thirteenth Defense**

3 13. The product at issue was not in a defective condition or unreasonably dangerous at the
4 time it left the control of the manufacturer or seller.

5 **Fourteenth Defense**

6 14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit
7 for its intended use and the warnings and instructions accompanying Bextra® at the time of
8 the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved
9 usages.

10 **Fifteenth Defense**

11 15. Plaintiff's causes of action are barred, in whole or in part, by the lack of a defect as the
12 Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable
13 standard of care.

14 **Sixteenth Defense**

15 16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use
16 of the product Bextra® after the product left the control of Defendant and any liability of
17 Defendant is therefore barred.

18 **Seventeenth Defense**

19 17. Plaintiff's alleged injuries/damages were not caused by any failure to warn on the part
20 of Defendant.

21 **Eighteenth Defense**

22 18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent
23 conditions unrelated to Bextra®.

24 **Nineteenth Defense**

25 19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore,
26 the doctrine of assumption of the risk bars or diminishes any recovery.

27 **Twentieth Defense**

28 20. Plaintiff is barred from recovering against Defendant because Plaintiff's claims are

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San Francisco, CA 94111

preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred, in whole or in part, under the applicable state law because the subject pharmaceutical product at issue were subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred, in whole or in part, by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred, in whole or in part, because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred, in whole or in part, because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred, in whole or in part, because the subject pharmaceutical

1 product at issue “provides net benefits for a class of patients” within the meaning of
2 Restatement (Third) of Torts: Products Liability, § 6, Comment f.

3 **Twenty-eighth Defense**

4 28. Plaintiff’s claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
5 Products Liability.

6 **Twenty-ninth Defense**

7 29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead
8 facts sufficient under the law to justify an award of punitive damages.

9 **Thirtieth Defense**

10 30. Defendant affirmatively avers that the imposition of punitive damages in this case
11 would violate Defendant’s rights to procedural due process under the Fourteenth Amendment
12 of the United States Constitution and the Constitutions of the States of California and Kansas,
13 and would additionally violate Defendant’s rights to substantive due process under the
14 Fourteenth Amendment of the United States Constitution.

15 **Thirty-first Defense**

16 31. Plaintiff’s claims for punitive damages are barred, in whole or in part, by the Fifth and
17 Fourteenth Amendments to the United States Constitution.

18 **Thirty-second Defense**

19 32. The imposition of punitive damages in this case would violate the First Amendment to
20 the United States Constitution.

21 **Thirty-third Defense**

22 33. Plaintiff’s punitive damage claims are preempted by federal law.

23 **Thirty-fourth Defense**

24 34. In the event that reliance was placed upon Defendant’s nonconformance to an express
25 representation, this action is barred as there was no reliance upon representations, if any, of
26 Defendant.

27 **Thirty-fifth Defense**

28 35. Plaintiff failed to provide Defendant with timely notice of any alleged nonconformance

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1 to any express representation.

2 **Thirty-sixth Defense**

3 36. To the extent that Plaintiff's claims are based on a theory providing for liability
4 without proof of causation, the claims violate Defendant's rights under the United States
5 Constitution.

6 **Thirty-seventh Defense**

7 37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any,
8 and labeling with respect to the subject pharmaceutical product were not false or misleading
9 and, therefore, constitute protected commercial speech under the applicable provisions of the
10 United States Constitution.

11 **Thirty-eighth Defense**

12 38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly
13 caused injuries asserted in the Complaint, punitive damages are barred or reduced by
14 applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the
15 due process protections afforded by the United States Constitution, the excessive fines clause
16 of the Eighth Amendment of the United States Constitution, the Commerce Clause of the
17 United States Constitution, and the Full Faith and Credit Clause of the United States
18 Constitution, and applicable provisions of the Constitutions of the States of Kansas and
19 California. Any law, statute, or other authority purporting to permit the recovery of punitive
20 damages in this case is unconstitutional, facially and as applied, to the extent that, without
21 limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's
22 discretion in determining whether to award punitive damages and/or the amount, if any; (2) is
23 void for vagueness in that it failed to provide adequate advance notice as to what conduct will
24 result in punitive damages; (3) permits recovery of punitive damages based on out-of-state
25 conduct, conduct that complied with applicable law, or conduct that was not directed, or did
26 not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an
27 amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff
28 and to the amount of compensatory damages, if any; (5) permits jury consideration of net

1 worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient
2 standards to be applied by the trial court in post-verdict review of any punitive damages
3 awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages
4 awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without
5 limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v.*
6 *Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S.
7 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

8 **Thirty-ninth Defense**

9 39. The methods, standards, and techniques utilized with respect to the manufacture,
10 design, and marketing of Bextra®, if any, used in this case, included adequate warnings and
11 instructions with respect to the product's use in the package inserts and other literature, and
12 conformed to the generally recognized, reasonably available, and reliable state of the
13 knowledge at the time the product was marketed.

14 **Fortieth Defense**

15 40. The claims asserted in the Complaint are barred because Bextra® was designed, tested,
16 manufactured and labeled in accordance with the state-of-the-art industry standards existing at
17 the time of the sale.

18 **Forty-first Defense**

19 41. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information
20 and belief, such injuries and losses were caused by the actions of persons not having real or
21 apparent authority to take said actions on behalf of Defendant and over whom Defendant had
22 no control and for whom Defendant may not be held accountable.

23 **Forty-second Defense**

24 42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
25 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
26 intended, and was distributed with adequate and sufficient warnings.

27 **Forty-third Defense**

28 43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches,

1 waiver, and/or estoppel.

2 **Forty-fourth Defense**

3 44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the
4 pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or
5 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were
6 independent of or far removed from Defendant's conduct.

7 **Forty-fifth Defense**

8 45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®
9 did not proximately cause injuries or damages to Plaintiff.

10 **Forty-sixth Defense**

11 46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff
12 did not incur any ascertainable loss as a result of Defendant's conduct.

13 **Forty-seventh Defense**

14 47. The claims asserted in the Complaint are barred, in whole or in part, because the
15 manufacturing, labeling, packaging, and any advertising of the product complied with the
16 applicable codes, standards and regulations established, adopted, promulgated or approved by
17 any applicable regulatory body, including but not limited to the United States, any state, and
18 any agency thereof.

19 **Forty-eighth Defense**

20 48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the
21 product labeling contained the information that Plaintiff contends should have been provided.

22 **Forty-ninth Defense**

23 49. The claims asserted in the Complaint are barred because the utility of Bextra®
24 outweighed its risks.

25 **Fiftieth Defense**

26 50. Plaintiff's damages, if any, are barred or limited by the payments received from
27 collateral sources.

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Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Fifty-first Defense

51. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Art. VI, cl. 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendant states on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendant states on information and belief that any injuries, losses, or damages suffered by Plaintiff were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendant. Therefore, Plaintiff's recovery against Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Defendant states that to the best of Defendant's knowledge, information, and belief, reasonable discovery will likely produce evidentiary support demonstrating that the fault of others for whom Defendant is not responsible directly caused or contributed to Plaintiff's injuries, and the fault of Plaintiff and such others should be compared pursuant to K.S.A. § 60-258(a).

Fifty-ninth Defense

59. Plaintiff's claims are barred by Defendant's compliance with relevant legislative and administrative regulatory safety standards authorized by the Kansas Product Liability Act, K.S.A. §§ 60-3301, et seq.

Sixtieth Defense

60. To the extent Plaintiff contends that Plaintiff is entitled to damages pursuant to a personal injury claim, which contention is expressly denied, claims for non-economic losses may not exceed \$250,000 pursuant to K.S.A. § 60-19a.

Sixty-first Defense

61. Plaintiff's claims against Defendant are barred by K.S.A. § 60-3306.

Sixty-second Defense

62. Plaintiff's claims against Defendant are limited by K.S.A. § 60-1903.

Sixty-third Defense

63. Defendant states that any award of punitive damages in this case would violate Defendant's procedural and substantive due process rights because there are insufficient circumstances in this case to support the reasonableness of an award of punitive damages and there are inadequate legal and procedural constraints imposed on the fact finder's discretion to impose such awards. The standard for punitive damages in Kansas lack sufficient objective criteria and procedural safeguards to give a jury adequate criteria or an appropriate range of proportionality regarding punitive damages.

Sixty-fourth Defense

64. Defendant states that it would violate Defendant's rights guaranteed by the United States Constitution and the Kansas Constitution to impose punitive damages against it which are penal in nature by requiring a burden of proof on Plaintiff which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases. In the alternative, entitlement to such damages would be provided by a "clear" and "convincing" standard of proof, in view of insufficient substantive and procedural protections under Kansas law regarding punitive damages.

Sixty-fifth Defense

65. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiff's claims.

IV.**PRAYER**

WHEREFORE, Defendant prays for judgment as follows:

1. That Plaintiff takes nothing from Defendant by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendant be awarded its costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;

1 5. That any judgment for damages against Defendant in favor of Plaintiff be no greater
2 than an amount which equals their proportionate share, if any, of the total fault or other
3 liability which proximately caused Plaintiff's damages; and

4 6. That Defendant has such other and further relief as the Court deems appropriate.

5
6 July 16, 2008

GORDON & REES LLP

7
8 By: _____/s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
9 San Francisco, CA 94111
10 Telephone: (415) 986-5900
11 Fax: (415) 986-8054

12 July 16, 2008

TUCKER ELLIS & WEST LLP

13
14 By: _____/s/
15 Michael C. Zellers
16 michael.zellers@tuckerellis.com
17 515 South Flower Street, Suite 4200
18 Los Angeles, CA 90071-2223
19 Telephone: (213) 430-3400
20 Fax: (213) 430-3409

21
22 Attorneys for Defendant
23 PFIZER INC.
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25
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Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

JURY DEMAND

Defendant Pfizer Inc. hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

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GORDON & REES LLP

By: _____/s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

July 16, 2008

TUCKER ELLIS & WEST LLP

By: _____/s/
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendant
PFIZER INC.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111